

EXHIBIT A

Kimberly Kenton, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,)	
PELVIC REPAIR SYSTEM)	
PRODUCTS LIABILITY)	Master File No.
LITIGATION)	2:12-MD-02327
)	MDL 2327
)	
)	
)	JOSEPH R. GOODWIN
)	U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO:)	
THE CASES LISTED BELOW)	
)	
Mullins, et al. V.)	2:12-cv-02952
Ethicon, Inc., et al.)	
)	
Sprout, et al. V.)	2:12-cv-07924
Ethicon, Inc., et al.)	
)	
Iquinto v. Ethicon, Inc.,)	2:12-cv-09765
et al.)	
)	
Daniel, et al. V.)	2:13-cv-02565
Ethicon, Inc., et al.)	
)	
Dillon, et al. V.)	2:13-cv-02919
Ethicon, Inc., et al.)	
)	
Webb, et al. V. Ethicon,)	2:13-cv-04517
Inc., et al.)	
)	
Martinez v. Ethicon,)	2:13-cv-04730
Inc., et al.)	
)	
McIntyre, et al. V.)	2:13-cv-07283
Ethicon, Inc., et al.)	

CONTINUED VIDEOTAPED DEPOSITION OF KIMBERLY KENTON, M.D.
Friday, February 19, 2016, 8:10 a.m.

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<p>1 Q. Okay. And I think you said yesterday</p> <p>2 that you don't rely on anecdotal information to</p> <p>3 reach your opinions about the TVT mechanically-cut?</p> <p>4 A. I try not to.</p> <p>5 Q. Okay. And you don't rely on information</p> <p>6 from Ethicon, the manufacturer of the device, is</p> <p>7 that correct?</p> <p>8 A. That's correct.</p> <p>9 Q. And you don't rely on the information</p> <p>10 that is contained in the Instructions for Use, or</p> <p>11 the IFU, that accompanies the TVT mechanically-cut,</p> <p>12 is that right?</p> <p>13 A. That's correct.</p> <p>14 Q. Now, yesterday when I looked back at</p> <p>15 your testimony you said that one of the reasons</p> <p>16 that you had agreed to testify in the case was that</p> <p>17 you didn't believe that midurethral slings should</p> <p>18 be taken off the market or something to that</p> <p>19 effect. Do you remember that?</p> <p>20 A. I do.</p> <p>21 Q. Is that your opinion? Is that a correct</p> <p>22 statement of your opinion?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Who told you that this lawsuit</p>	<p>1 polypropylene midurethral sling, correct?</p> <p>2 A. That's correct, although much of the</p> <p>3 data that we rely upon is based upon</p> <p>4 mechanically-cut.</p> <p>5 Q. Okay. Let me talk to you about that a</p> <p>6 little bit. You must have read my mind.</p> <p>7 How many RCTs exist establishing the</p> <p>8 efficacy of the TVT mechanically-cut specifically?</p> <p>9 A. I don't think I can give you an exact</p> <p>10 number without going back to some, probably doing a</p> <p>11 PubMed search and giving you an exact number,</p> <p>12 because it would even -- even the Cochrane reports</p> <p>13 and the meta-analyses may miss some.</p> <p>14 But the Ward-Hilton data is all</p> <p>15 mechanically-cut. The better part of the SISTER is</p> <p>16 mechanically-cut. There is a Barber paper looking</p> <p>17 at I think transobturator versus retropubic. And</p> <p>18 based on the timing of that, I couldn't tell you</p> <p>19 for sure, but I think it's probably that reflects</p> <p>20 mechanically-cut.</p> <p>21 Q. Okay. When you say "the timing," why is</p> <p>22 the timing of the article important to you when</p> <p>23 discussing the mechanically-cut versus the</p> <p>24 laser-cut?</p>
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<p>1 was about taking all polypropylene midurethral</p> <p>2 slings off the market?</p> <p>3 A. Nobody.</p> <p>4 Q. You understand that's not what this</p> <p>5 lawsuit is about, correct?</p> <p>6 A. I do understand.</p> <p>7 Q. Okay. And if the TVT mechanically-cut</p> <p>8 device was taken off the market, it wouldn't affect</p> <p>9 your ability to offer surgical options to women for</p> <p>10 the treatment of stress urinary incontinence,</p> <p>11 correct?</p> <p>12 A. Can you please clarify.</p> <p>13 Q. Sure. If Ethicon stopped selling the</p> <p>14 TVT that's mechanically-cut, you would still be</p> <p>15 able to implant the TVT Exact into women, correct?</p> <p>16 A. Correct.</p> <p>17 Q. And you'd still be able to implant the</p> <p>18 Boston Scientific Advantage that you use into</p> <p>19 women, correct?</p> <p>20 A. Correct.</p> <p>21 Q. So, taking the TVT mechanically-cut off</p> <p>22 the market, even if that's what this case is about,</p> <p>23 wouldn't affect your ability to offer women a</p> <p>24 surgical treatment for SUI that included a</p>	<p>1 A. Because my understanding is that the</p> <p>2 laser-cut came out later. So, only</p> <p>3 mechanically-cut was available for a long time.</p> <p>4 Q. Okay. And what year is it your</p> <p>5 understanding that the laser-cut came on the</p> <p>6 market?</p> <p>7 A. I'm not sure.</p> <p>8 Q. So, you believe that the Ward-Hilton,</p> <p>9 some of the SISTER study and the Barber paper deals</p> <p>10 solely with mechanically-cut, is that right?</p> <p>11 A. I didn't say solely. I said majority of</p> <p>12 SISTER was mechanically-cut. There is no way to</p> <p>13 know when people switched over.</p> <p>14 Q. Okay. So, would you agree with me that</p> <p>15 in the SISTER study there is no way of really</p> <p>16 knowing how many of those devices were</p> <p>17 mechanically-cut and how many of those devices were</p> <p>18 laser-cut?</p> <p>19 A. That's correct. But having</p> <p>20 participated, we were well into the trial before</p> <p>21 laser-cut was even being introduced into the</p> <p>22 equation, at least in our sites.</p> <p>23 Q. Okay. So, for your site you know that</p> <p>24 there is --</p>

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<p>1 A. It's easier for me to --</p> <p>2 Q. That's fine.</p> <p>3 A. Oddly, I don't have it in the right</p> <p>4 file.</p> <p>5 I can pull it out of here. So much for</p> <p>6 my filing system.</p> <p>7 I will see if I can pull it up.</p> <p>8 THE WITNESS: Can we connect to the Internet</p> <p>9 here?</p> <p>10 MR. SNELL: Yeah. It's DBR WiFi.</p> <p>11 THE WITNESS: Might just be faster to PubMed</p> <p>12 it.</p> <p>13 MS. FITZPATRICK: It's why they call it the</p> <p>14 Windy City I guess. The windows shake.</p> <p>15 (WHEREUPON, discussion was had off</p> <p>16 the record.)</p> <p>17 THE WITNESS: I apologize for not being able</p> <p>18 to put my hand on this.</p> <p>19 BY MS. FITZPATRICK:</p> <p>20 Q. That's okay. If you don't have it, we</p> <p>21 can move on.</p> <p>22 A. Yeah. Like I can find it for you at</p> <p>23 some point, but I -- it's in this pile somewhere.</p> <p>24 Q. Okay. That's fine.</p>	<p>1 Q. So, we can -- we can move on.</p> <p>2 Of the RCTs that you have looked at for</p> <p>3 mechanically-cut TVT, how many of those had a</p> <p>4 primary endpoint of safety?</p> <p>5 A. In general, you're never going to have a</p> <p>6 primary endpoint of safety for doing a randomized</p> <p>7 controlled trial in something that has a rare</p> <p>8 outcome because you would have to enroll</p> <p>9 millions -- like thousands of women. So, usually</p> <p>10 you have to -- you primary on an efficacy outcome.</p> <p>11 Q. Okay. So, you're not --</p> <p>12 A. Unless something is a common</p> <p>13 complication, and then who would -- had high</p> <p>14 complication rates and then who would be doing an</p> <p>15 RCT? It would be unethical.</p> <p>16 Q. Okay. So, none of them have a primary</p> <p>17 endpoint of safety for the reasons that you have</p> <p>18 just discussed, is that right?</p> <p>19 A. You -- it's not a feasible trial design.</p> <p>20 You have to use a different type of study to</p> <p>21 evaluate that. That's where systematic reviews and</p> <p>22 meta-analyses become powerful.</p> <p>23 THE VIDEOGRAPHER: Excuse me, Doctor, if</p> <p>24 you're not using the laptop, could you move it</p>
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<p>1 So, it's your recollection that there is</p> <p>2 one RCT that compares the laser-cut TVT Retropubic</p> <p>3 to the mechanically-cut TVT Retropubic?</p> <p>4 A. I think it's an RCT. Like I said, I</p> <p>5 can't recall the paper --</p> <p>6 Q. Okay.</p> <p>7 A. -- specifically, but I -- there is -- I</p> <p>8 came across one comparator that I can remember.</p> <p>9 Q. Okay. And I think you said that you</p> <p>10 believe that that was an underpowered study where</p> <p>11 they couldn't confirm their conclusions --</p> <p>12 A. Yes.</p> <p>13 Q. -- is that right?</p> <p>14 A. I would -- I would rather than perhaps</p> <p>15 inaccurately cite the paper, I'd rather find the</p> <p>16 paper.</p> <p>17 Q. Okay.</p> <p>18 A. I didn't -- I didn't feel that it made a</p> <p>19 cogent argument that compelled me to lean one way</p> <p>20 or the other.</p> <p>21 Q. Okay. Why don't maybe at a break we can</p> <p>22 take a look for that. But I know that you have a</p> <p>23 time limitation today.</p> <p>24 A. Yeah.</p>	<p>1 away. That's fine. Thank you.</p> <p>2 BY MS. FITZPATRICK:</p> <p>3 Q. Now, Doctor, you offered an opinion</p> <p>4 yesterday that you believed that the laser-cut</p> <p>5 TVT Retropubic performed the same as the</p> <p>6 mechanically-cut TVT Retropubic. Do you recall</p> <p>7 that?</p> <p>8 A. I do.</p> <p>9 Q. And is that an opinion that you hold</p> <p>10 today?</p> <p>11 A. It is.</p> <p>12 Q. Is that based on any data that is</p> <p>13 available in the literature to support that</p> <p>14 opinion?</p> <p>15 A. The only small study that I recall</p> <p>16 coming across didn't -- wasn't compelling to</p> <p>17 support one versus the other.</p> <p>18 Q. So, what is the basis for your --</p> <p>19 A. And my clinical experience has not been</p> <p>20 that there's a difference.</p> <p>21 Q. I'm --</p> <p>22 A. My clinical experience hasn't been that</p> <p>23 there is a difference as well.</p> <p>24 Q. And your clinical experience, that would</p>

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<p>1 be the anecdotal experience that we had talked</p> <p>2 about yesterday and this morning, correct?</p> <p>3 A. That would be --</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. That would be every surgeon who is</p> <p>7 giving their overall clinical experience. I would</p> <p>8 say in general my experiences are probably slightly</p> <p>9 less anecdotal because I do report outcomes.</p> <p>10 BY MS. FITZPATRICK:</p> <p>11 Q. Have you reported outcomes comparing the</p> <p>12 laser-cut to the mechanically-cut?</p> <p>13 A. As I've said, I'm only familiar with one</p> <p>14 paper in the literature that directly compares</p> <p>15 those two, for that purpose.</p> <p>16 Q. Okay. I understand that, but you said</p> <p>17 that you believe your experiences are probably</p> <p>18 slightly less anecdotal because you do report</p> <p>19 outcomes, correct?</p> <p>20 So, what I am asking is have you</p> <p>21 reported outcomes that compare the TVT</p> <p>22 mechanically-cut versus the TVT laser-cut?</p> <p>23 A. I have not.</p> <p>24 Q. Okay. And you don't track that actually</p>	<p>1 I came -- I transferred institutions and we are</p> <p>2 using exclusively laser-cut.</p> <p>3 Q. Okay. But I have a slightly different</p> <p>4 question than that.</p> <p>5 A. Okay.</p> <p>6 Q. Post-2006 how did you know whether you</p> <p>7 were implanting a mechanically-cut or a laser-cut</p> <p>8 into women?</p> <p>9 A. That's a fair point.</p> <p>10 Q. So, at your prior -- so, before</p> <p>11 laser-cut hit the market, you know that you</p> <p>12 implanted only mechanically-cut, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. You didn't start to implant the TVT</p> <p>15 until the mid-2000s, correct?</p> <p>16 A. Right. So, the only way I would know</p> <p>17 which one I was using is to go back and pull the</p> <p>18 records.</p> <p>19 Q. Okay. Which you haven't done?</p> <p>20 A. I have not done.</p> <p>21 Q. Okay. Have you -- do you know who</p> <p>22 Dr. Nilsson is?</p> <p>23 A. Nilsson that has published the papers?</p> <p>24 Q. Yes.</p>
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<p>1 in either your academic work or in your clinical</p> <p>2 work, correct?</p> <p>3 A. No, actually, we actually do track our</p> <p>4 outcomes.</p> <p>5 Q. Okay. Do you track your outcomes in</p> <p>6 your clinical work?</p> <p>7 A. I do. As I said, we see our patients</p> <p>8 back yearly.</p> <p>9 Q. Okay. I'm asking you something a little</p> <p>10 different.</p> <p>11 Do you track outcomes for patients</p> <p>12 looking at mechanically-cut versus laser-cut?</p> <p>13 A. Well, if you tracked -- the only way you</p> <p>14 can track that type of an outcome is if you're</p> <p>15 going to retrospectively look at the patients</p> <p>16 who've had implanted, and we do -- we do keep those</p> <p>17 data and we see people back yearly.</p> <p>18 Q. Okay. You keep the data on who's had a</p> <p>19 mechanically-cut versus who's had a laser-cut, is</p> <p>20 that right?</p> <p>21 A. Well, for me it's been rather simple</p> <p>22 because I practice at one institution and everyone</p> <p>23 got a mechanically-cut TVT because that was the</p> <p>24 device that I was using. And then I came here and</p>	<p>1 A. I don't know him personally.</p> <p>2 Q. Do you know who he is?</p> <p>3 A. I know his work.</p> <p>4 Q. Okay. Do you consider that work to be</p> <p>5 reliable?</p> <p>6 A. I think that for the -- yes. I mean,</p> <p>7 it's observational cohort data, so it's not as good</p> <p>8 as RCT data. But you're never going to be able to</p> <p>9 do a randomized controlled trial and follow women</p> <p>10 for 10 or 20 years because no one is going to pay</p> <p>11 for it.</p> <p>12 And as the SISTER trial showed, women</p> <p>13 that are happy and incontinent tend to not enroll</p> <p>14 in long-term follow-up.</p> <p>15 Q. So, Doctor -- but you are familiar with</p> <p>16 Dr. Nilsson's work, is that right?</p> <p>17 A. I am.</p> <p>18 Q. Are you familiar with any of</p> <p>19 Dr. Nielsen's opinions about the differences, if</p> <p>20 any, between laser-cut and mechanically-cut mesh?</p> <p>21 A. No.</p> <p>22 Q. Has anyone from Ethicon ever shared that</p> <p>23 information with you?</p> <p>24 A. If they have, I don't recall it.</p>

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<p>1 MS. FITZPATRICK: Burt, can I just do one</p> <p>2 thing superquick.</p> <p>3 MR. SNELL: What?</p> <p>4 BY MS. FITZPATRICK:</p> <p>5 Q. This CV that you have, is that your most</p> <p>6 up-to-date copy of your CV that was attached to</p> <p>7 your report?</p> <p>8 A. I update it like every probably monthly.</p> <p>9 So, it's probably a month or so out of date.</p> <p>10 MS. FITZPATRICK: If I can just get the most</p> <p>11 recent copy of her CV, then we're all set. Thank</p> <p>12 you.</p> <p>13 BY THE WITNESS:</p> <p>14 A. It's not wildly different.</p> <p>15 EXAMINATION</p> <p>16 BY MR. SNELL:</p> <p>17 Q. Dr. Kenton, Burt Snell representing</p> <p>18 Ethicon and Johnson & Johnson. I just want to</p> <p>19 follow-up on a couple quick topics.</p> <p>20 We talked primarily about the Schimpf</p> <p>21 systematic review today. Did you cite to other</p> <p>22 systematic reviews and meta-analyses in support of</p> <p>23 your opinions and your report?</p> <p>24 A. I did.</p>	<p>1 Cochrane review or others, show a lower rate of</p> <p>2 those complications with the TVT as compared to --</p> <p>3 A. Yes.</p> <p>4 Q. -- the autologous or the Burch?</p> <p>5 You were asked about mesh exposure.</p> <p>6 A. As does the SISTER and TOMUS trials.</p> <p>7 Q. You were asked about mesh exposure and</p> <p>8 you also talked about suture erosions. Do you</p> <p>9 classify those as wound complications?</p> <p>10 A. Yes.</p> <p>11 Q. Did -- were wound complications assessed</p> <p>12 in both the SISTER and TOMUS trials?</p> <p>13 A. They were and they were similar. They</p> <p>14 were just different places that the wound</p> <p>15 complication occurred.</p> <p>16 Q. And do you recall whether for wound</p> <p>17 complications not requiring surgical intervention,</p> <p>18 whether there was a higher rate with autologous</p> <p>19 pubovaginal sling, Burch or --</p> <p>20 A. Wound complications not requiring</p> <p>21 reoperation was higher in the autologous fascial</p> <p>22 sling arm. Wound complications requiring</p> <p>23 reoperations were similar.</p> <p>24 Q. You were asked some questions about</p>
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<p>1 Q. Would you turn to page 36 for the</p> <p>2 American Urologic Association's systematic review</p> <p>3 and guideline.</p> <p>4 You were asked some questions about pain</p> <p>5 and sexual dysfunction and rates, how they compare</p> <p>6 amongst the different options.</p> <p>7 Did you assess those issues on page 36</p> <p>8 and 37 of your report?</p> <p>9 A. I did.</p> <p>10 Q. How does the midurethral sling compare</p> <p>11 to the autologous pubovaginal sling and the Burch?</p> <p>12 A. For what?</p> <p>13 Q. For pain and sexual dysfunction.</p> <p>14 A. Do you want me to recite the actual</p> <p>15 percentages that I gave?</p> <p>16 Q. What is your assessment of what those</p> <p>17 percentages show? Was midurethral sling less than</p> <p>18 the other procedures --</p> <p>19 A. Yeah.</p> <p>20 Q. -- or more than?</p> <p>21 A. Less than, which is consistent with.</p> <p>22 Q. You were asked some questions about</p> <p>23 voiding dysfunction and retention. Do some of the</p> <p>24 other systematic reviews, if any, like Ogah, the</p>	<p>1 mechanical-cut versus laser-cut. Now, and there</p> <p>2 were questions about certain randomized controlled</p> <p>3 trials, and I think you testified that the earlier</p> <p>4 data and the longer-term data are for the</p> <p>5 mechanical-cut TVT, is that right?</p> <p>6 A. Yes.</p> <p>7 Q. If you look at Table 1 of Schimpf.</p> <p>8 A. Okay.</p> <p>9 Q. You were saying that one could look at</p> <p>10 the years when those studies were performed to</p> <p>11 assess whether they were mechanical-cut or came</p> <p>12 later after 2007 for --</p> <p>13 A. Correct.</p> <p>14 Q. -- laser-cut.</p> <p>15 So, in Table 1 for the various TVT</p> <p>16 studies, do the majority of those appear to be</p> <p>17 mechanical-cut?</p> <p>18 A. They do.</p> <p>19 Q. At page 11 and 12 of your expert report</p> <p>20 you were asked some questions about are there any</p> <p>21 specific studies that reference a difference, if</p> <p>22 any, in complications for laser or mechanical-cut</p> <p>23 TVT?</p> <p>24 A. Oh, there it is.</p>

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<p>1 Q. My question to you is: Did you identify</p> <p>2 those particular studies where there was commentary</p> <p>3 on laser versus mechanical-cut --</p> <p>4 A. I did.</p> <p>5 Q. -- that you found on your PubMed</p> <p>6 searching?</p> <p>7 You cite to a study in 2006 comparing</p> <p>8 laser-cut to mechanical-cut TVT-O and you say which</p> <p>9 is the same material as mechanically-cut TVT.</p> <p>10 Did the mechanical-cut tape have any</p> <p>11 higher rate of complication for mesh exposures?</p> <p>12 A. It had lower.</p> <p>13 Q. On the next page you cite to another</p> <p>14 randomized trial with mechanically-cut TVT tape in</p> <p>15 the TVT-O and then a TVT-Secur which you identify</p> <p>16 as laser-cut.</p> <p>17 Did the mechanical-cut TVT tape have a</p> <p>18 higher rate of dyspareunia than the laser-cut?</p> <p>19 A. No.</p> <p>20 Q. Have you continually looked at the</p> <p>21 medical literature and studies before 2007 when</p> <p>22 laser-cut mesh became available as well as after?</p> <p>23 A. I have.</p> <p>24 Q. Have you seen any clinically significant</p>	<p>1 TVT?</p> <p>2 A. I would like to get the actual numbers.</p> <p>3 Can you ask something else while I look?</p> <p>4 Q. Yes. You were asked questions about</p> <p>5 whether there could be prolonged pain or death with</p> <p>6 the autologous pubovaginal sling, and I think you</p> <p>7 stated that off the top of your head you couldn't</p> <p>8 point to or recall a specific article in the</p> <p>9 literature that reported those complications.</p> <p>10 Do you recall giving that testimony?</p> <p>11 A. I do recall that.</p> <p>12 Q. Do you recall actually one of the</p> <p>13 studies, it may have been mentioned, I thought it</p> <p>14 was, by lead author Chaikin regarding pubovaginal</p> <p>15 fascial slings?</p> <p>16 A. Yeah, that was in Dr. Blaivas' report.</p> <p>17 Q. Okay. If you look at Table 4,</p> <p>18 "Complications," do they in fact report a death as</p> <p>19 well as prolonged pain with the autologous</p> <p>20 pubovaginal sling?</p> <p>21 A. They do.</p> <p>22 Q. Do they also state that since there is</p> <p>23 no exact method of determining how much tension to</p> <p>24 put on that sling during surgery, one must rely on</p>
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<p>1 difference in the rates of complications with TVT</p> <p>2 that were reported before 2007 as opposed to after?</p> <p>3 A. Definitely not.</p> <p>4 Q. Are the rates in the large systematic</p> <p>5 reviews and Cochrane reviews like 4 Tommaselli, are</p> <p>6 the rates of complications, particularly let's take</p> <p>7 exposure, consistent or inconsistent with the rates</p> <p>8 reported before 2007?</p> <p>9 A. Consistent.</p> <p>10 Q. You were asked questions about the mesh</p> <p>11 folding or curling. In your analysis did you see</p> <p>12 any Level 1 data that attributed mesh folding,</p> <p>13 curling or roping to a complication?</p> <p>14 A. No.</p> <p>15 Q. You were asked about voiding</p> <p>16 dysfunction. Have you assessed the voiding</p> <p>17 dysfunction and the rate for surgery needed to</p> <p>18 address voiding dysfunction in SISTER and TOMUS</p> <p>19 studies?</p> <p>20 A. We did.</p> <p>21 Q. And what is your opinion as to what</p> <p>22 those show, if anything, with regard to a</p> <p>23 difference in the rates between the autologous</p> <p>24 pubovaginal slings you were asked about and the</p>	<p>1 experience to make judgments?</p> <p>2 A. Yes.</p> <p>3 Q. Now, is that consistent or inconsistent</p> <p>4 with your opinion about how you tension TVT slings?</p> <p>5 A. That's consistent with what I've said --</p> <p>6 Q. Is that consistent --</p> <p>7 A. -- yesterday.</p> <p>8 Q. Is that consistent or inconsistent with</p> <p>9 what you said as a basis for your use of TVT that</p> <p>10 you had already been trained and experienced in</p> <p>11 fascial slings?</p> <p>12 MS. FITZPATRICK: I'm going to object at this</p> <p>13 point to not only is this leading, Mr. Snell, you</p> <p>14 are basically testifying for the witness in an</p> <p>15 attempt to change her testimony from before and</p> <p>16 what she did and it's completely improper.</p> <p>17 MR. SNELL: It's not. I'm asking. This is</p> <p>18 perfectly good, solid questioning.</p> <p>19 MS. FITZPATRICK: Completely leading.</p> <p>20 MR. SNELL: Actually, consistent or</p> <p>21 inconsistent, if you look, is not leading. All</p> <p>22 right. So that's the question. She can answer any</p> <p>23 way she wants to. Is it consistent or</p> <p>24 inconsistent.</p>

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<p>1 MS. FITZPATRICK: You want to spend your</p> <p>2 witness' time acting like this, you go right ahead.</p> <p>3 THE WITNESS: So --</p> <p>4 MS. FITZPATRICK: But maybe it's better to let</p> <p>5 her answer the questions and get out.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Voiding dysfunction leading to surgical</p> <p>8 revision after a pubovaginal sling in RCTs was 6%</p> <p>9 compared to 2.7% after retropubic midurethral.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. And you are referencing voiding</p> <p>12 dysfunction in the SISTER and TOMUS trials?</p> <p>13 A. I am.</p> <p>14 Q. And, so, my question then -- I think I</p> <p>15 have just two more.</p> <p>16 When you mentioned that you were trained</p> <p>17 on the autologous sling and learned how to tension</p> <p>18 slings and then you transitioned to TVT and it was</p> <p>19 not a significant difference in your opinion, is</p> <p>20 that consistent or inconsistent with the statement</p> <p>21 in the Chaikin paper that since there is no exact</p> <p>22 method of determining tension to put on an</p> <p>23 autologous sling, one must rely on experience?</p> <p>24 A. That's consistent.</p>	<p>1 A. I believe that's consistent with my</p> <p>2 testimony that it should be individualized.</p> <p>3 MR. SNELL: Thank you. That's -- is there</p> <p>4 anything else?</p> <p>5 I'm just going to mark for the record --</p> <p>6 let's mark these as the next two in line.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. A question was raised, Doctor, about --</p> <p>9 Ms. Fitzpatrick gave you a sheet of paper that</p> <p>10 seemed to suggest that there may be a \$5,000</p> <p>11 contract with you between you and Ethicon.</p> <p>12 I'm going to mark for the record</p> <p>13 additional Ethicon documents that you weren't shown</p> <p>14 which on their face state --</p> <p>15 A. This is the one from 2007?</p> <p>16 Q. Yes. Which on their face state that</p> <p>17 there was no payment made, zero dollars. Just for</p> <p>18 the record.</p> <p>19 A. Good.</p> <p>20 MR. SNELL: We will mark those seriatim.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Then my recollection was correct.</p> <p>23 (WHEREUPON, certain documents were</p> <p>24 marked Kenton Deposition Exhibit</p>
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<p>1 Q. You were shown the IFU and asked</p> <p>2 questions that seem to imply that there was a</p> <p>3 discrepancy in the language about tensioning. Do</p> <p>4 you recall that?</p> <p>5 MS. FITZPATRICK: Objection; misrepresents the</p> <p>6 statement, the question.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. Do you recall in general the discussion</p> <p>9 with --</p> <p>10 A. I do recall --</p> <p>11 Q. -- Ms. Fitzpatrick?</p> <p>12 A. -- about the IFU discussion.</p> <p>13 Q. I want to read something from the IFU to</p> <p>14 you. It says -- that you weren't read -- "This</p> <p>15 device should be used only by physicians trained in</p> <p>16 the surgical treatment of stress urinary</p> <p>17 incontinence. These instructions are recommended</p> <p>18 for general use of the device. Variations in use</p> <p>19 may occur in specific procedures due to individual</p> <p>20 technique and patient anatomy."</p> <p>21 My question to you is: Is that</p> <p>22 consistent or inconsistent with your opinions on</p> <p>23 how you in fact tension TVT for your different</p> <p>24 patients?</p>	<p>1 No. 21, Ethicon document, "All</p> <p>2 active contracts for 2008 through</p> <p>3 Nov. 19, 2008"; Bates No.</p> <p>4 Eth.Mesh.05013617, and No. 22,</p> <p>5 11/11/2010 Ethicon document re</p> <p>6 contracts; no Bates numbers.)</p> <p>7 MR. SNELL: That's it.</p> <p>8 MS. FITZPATRICK: Are you done testifying,</p> <p>9 Mr. Snell?</p> <p>10 MR. SNELL: I'm not testifying. I was</p> <p>11 questioning.</p> <p>12 FURTHER EXAMINATION</p> <p>13 BY MS. FITZPATRICK:</p> <p>14 Q. Turn to page 11 of your report.</p> <p>15 You don't cite this 2006 study. What is</p> <p>16 it?</p> <p>17 A. What do you mean I don't cite it?</p> <p>18 Q. I don't see a footnote that tells me</p> <p>19 what study --</p> <p>20 A. I didn't put the reference in?</p> <p>21 Q. No. What study is it?</p> <p>22 A. I mean, if I did have the reference,</p> <p>23 I'll have to go back and pull it from my file.</p> <p>24 Q. Do you believe that it's -- it would be</p>

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<p>1 appropriate for me to use data on complication 2 rates related to the ObTape and as a basis for what 3 I can expect out of complications from a TVT 4 device? 5 A. I believe that ObTape has higher erosion 6 rates than TVT. 7 Q. Okay. So, why would you use a paper 8 that's comparing the erosion rates of an ObTape 9 laser-cut to a TVT-O mechanical-cut to support your 10 opinion that there is no difference between the 11 TVT Retropubic mechanically-cut and the TVT 12 laser-cut? 13 A. Because there are very few data about 14 actually mechanically-cut versus laser-cut, and 15 that's about as good as the data is going to get. 16 Q. That's the best you can get. But you 17 agree with me, that's not a very good comparison, 18 is it? 19 A. It's not any better than the -- it's -- 20 to me it's not better or worse than the theories 21 that an engineer who has never touched a patient 22 has. 23 Q. Is that sufficient data for you as a 24 surgeon to rely on to make the determination that</p>	<p>1 is a difference, and there is a propensity of data 2 to support the mechanically-cut TVT is safe. 3 BY MS. FITZPATRICK: 4 Q. Okay. Do you believe that a study 5 comparing an ObTape laser-cut group to a 6 mechanically-cut TVT-O group is an appropriate 7 comparator or data to use when trying to determine 8 the clinical performance differences between the 9 TVT-R mechanical-cut and the TVT-R laser-cut? 10 MR. SNELL: Objection; form, asked and 11 answered. 12 BY THE WITNESS: 13 A. I don't believe that there are any 14 compelling data to use to compare those two. 15 BY MS. FITZPATRICK: 16 Q. Okay. Including this 2006 study that 17 you cite, correct? 18 A. Correct. It's the only thing that's out 19 there -- 20 Q. Thank you. 21 A. -- which is why I included it. 22 MS. FITZPATRICK: Nothing further. 23 THE VIDEOGRAPHER: Okay. 24 MR. SNELL: That's it. Thank you.</p>
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<p>1 there is no difference between the mechanically-cut 2 TVT-R and the mechanically-cut -- or the laser-cut 3 TVT-R? 4 A. As I've testified numerous times, most 5 of the data on which I made my decision to 6 transition to midurethral sling as well as a good 7 portion of the outcome data is on mechanically-cut. 8 So, I make my decisions not based on a 9 little itemized study but, rather, on the multitude 10 of the outcome data. 11 Q. Dr. Kenton, if we focus on what I'm 12 asking you, you're going to get out of here really 13 fast. 14 A. Great. 15 Q. TVT laser-cut versus TVT 16 mechanically-cut. 17 A. There is no -- 18 Q. Is there any data that supports your 19 opinion that there is no difference between the 20 clinical performance of the TVT-R mechanically-cut 21 and the TVT-R laser-cut? 22 MR. SNELL: Asked and answered. 23 BY THE WITNESS: 24 A. There is no data to support that there</p>	<p>1 THE VIDEOGRAPHER: The time is 12:15 p.m. 2 This is the end of the deposition, Volume 2 of the 3 deposition of Dr. Kimberly Kenton, and we're going 4 off the video record. 5 (Time Noted: 12:15 p.m.) 6 FURTHER DEPONENT SAITH NAUGHT. 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

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<p>1 I, CORINNE T. MARUT, C.S.R. No. 84-1968, 2 Registered Professional Reporter and Certified 3 Shorthand Reporter, do hereby certify: 4 That previous to the commencement of the 5 examination of the witness, the witness was duly 6 sworn to testify the whole truth concerning the 7 matters herein; 8 That the foregoing deposition transcript 9 was reported stenographically by me, was thereafter 10 reduced to typewriting under my personal direction 11 and constitutes a true record of the testimony 12 given and the proceedings had; 13 That the said deposition was taken 14 before me at the time and place specified; 15 That the reading and signing by the 16 witness of the deposition transcript was agreed 17 upon as stated herein; 18 That I am not a relative or employee or 19 attorney or counsel, nor a relative or employee of 20 such attorney or counsel for any of the parties 21 hereto, nor interested directly or indirectly in 22 the outcome of this action. 23 It was requested before completion of 24 the deposition that the witness, KIMBERLY KENTON, M.D., have the opportunity to read and sign the deposition transcript.</p> <p>CORINNE T. MARUT, Certified Reporter</p> <p>(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>	<p>1 - - - - - 2 E R R A T A 3 - - - - - 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____</p>
<p>Page 432</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. You 5 should state the reason in the appropriate space on 6 the errata sheet for any corrections that are made. 7 After doing so, please sign the errata 8 sheet and date it. 9 You are signing same subject to the 10 changes you have noted on the errata sheet, which 11 will be attached to your deposition. 12 It is imperative that you return the 13 original errata sheet to the deposing attorney 14 within thirty (30) days of receipt of the 15 deposition transcript by you. If you fail to do 16 so, the deposition transcript may be deemed to be 17 accurate and may be used in court. 18 19 20 21 22 23 24</p>	<p>Page 434</p> <p>1 2 ACKNOWLEDGMENT OF DEPONENT 3 4 I, KIMBERLY KENTON, M.D., do hereby 5 certify under oath that I have read the foregoing 6 pages, and that the same is a correct transcription 7 of the answers given by me to the questions therein 8 propounded, except for the corrections or changes 9 in form or substance, if any, noted in the attached 10 Errata Sheet. 11 12 13 _____ 14 KIMBERLY KENTON, M.D. DATE 15 16 17 Subscribed and sworn 18 to before me this 19 _____ day of _____, 20____. 20 My commission expires: _____ 21 22 23 24 _____ Notary Public</p>

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